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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/611,551

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Susan I. Shelso

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EXAMINER

TYSON, MELANIE RUANO

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

05/30/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/611,551

Applicant(s)

SHELSON, SUSAN I.

Examiner

Melanie Tyson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 16-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 16-32 is/are rejected.
- 7) ☒ Claim(s) 28 and 29 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 3/19/07 & 4/19/07.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

This action is in response to applicant's amendments received on 23 January 2007.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites the newly added limitation "the stent abuts the hub region." Since the phrase "for engaging a stent in a stent delivery catheter prior to delivery" corresponds to the intended use of the grip, the stent has not been positively claimed. Therefore, it is unclear as to whether or not the stent is part of the invention.
3. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 3 recites the limitation "the first end" in line 2. There is insufficient antecedent basis for this limitation in the claim.
4. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Amended claim 10 no longer positively claims a stent, yet still describes the position of the stent with respect to the grip. Therefore, it is unclear as to whether or not the stent is part of the invention.

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Claim Objections

5. Claim 28 is objected to because of the following informalities: claim 28 contains a typographical error. Replace "method" with --grip--. Appropriate correction is required.
6. Claim 29 is objected to because of the following informalities: claim 29 contains a typographical error. Replace "method" with --stent delivery system--. Appropriate correction is required.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-3, 7-14, 22-24, and 29-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Ravenscroft (Patent No. 5,702,418). Ravenscroft discloses a stent delivery system (see entire document) comprising a catheter having an inner shaft (for example, see Figure 4), a retractable sheath (for example, see Figures 1, 4, and 5, element 24), at least one radiopaque grip member (for example, see column 7, lines 42-59) having a substantially tapered body region (17; for example, see Figure 5) and a hub region (13) having an outer diameter (the point where stent 20 abuts) greater than the outer diameter of the body region (for example, see Figures 1 and 5), and an

expandable stent (20) comprising a plurality of struts (for example, see Figure 5) disposed about the inner shaft and engaged to at least a portion of the body region (17), wherein the stent (20) abuts the hub region (13) during use (for example, see Figure 1) and the outer diameter of the hub region (13) is greater than the outer diameter of the stent (20) when the stent (20) is in an unexpanded state (for example, see Figure 1). With further respect to claim 13, the grip member disclosed by Ravenscroft is inherently capable of reducing the longitudinal force the catheter exerts on the struts, since the grip member reduces the potential space between the inner catheter shaft and the retractable sheath.

9. Claims 1-3, 6-10, 25, and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Cox et al. (US 2003/0212451 A1). Cox et al. disclose a grip (see entire document) constructed from polymeric material (polyether block amides; paragraph 79) for engaging a stent (for example, see Figure 18) comprising a body region tapered from a first end (defined at a point midway between tapered edge 101) to a second end (defined at a point next to marker 42), a hub region (defined as the second half of tapered edge 101 extending through distal end 108, in which the region at the crest of tapered edge 101 has a diameter greater than the diameter of the body region), and a radiopaque portion (104; for example, see paragraph 79). Cox et al. further disclose a catheter (refer to Figure 1 for illustration) having an inner shaft (for example, see Figure 18, element 35) and a grip engaged to the inner shaft (35), wherein the grip defines at least a portion of a stent mounting region of the inner shaft (for example, see Figure 18) and an outer diameter of the hub region is greater than an outer diameter of an

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unexpanded stent (refer to Figure 1 for an illustration of an outer diameter of an unexpanded stent). The functional limitation "during use, the stent abuts the hub region" has been given limited weight, wherein the hub of Cox is capable of abutting a stent if one desires to place the stent in this configuration.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox et al. Cox et al. disclose the device as described above, however, fails to disclose the specific hardness of the grip. It is well known in the art that materials such as polyether block amide may have a hardness within the ranges claimed. It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the grip with a hardness of about 60 to about 90, or of 70 to about 90, since it

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has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

13. Claims 16-18, 21, 26, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ravenscroft in view of Gunderson (US 2004/0204749 A1).

Ravenscroft disclose a grip as described above, however, do not disclose two grip members disposed about the inner shaft of the catheter. Gunderson teaches a stent delivery system (see entire document) comprising grips (for example, see Figure 8) constructed of polymeric material (for example, see paragraph 37; for example, PEBAX) for engaging a stent. Figure 8 shows a first grip (10) and a second grip (not labeled), with the second end of the body region of the first grip being substantially adjacent to the second end of the body region of the second grip. Figure 8 also shows a stent (26), where in the unexpanded state the first end portion of the stent (26) is engaged to at least a portion of the body region of the first grip (10), and the second end portion of the stent is engaged to at least a portion of the body region of the second grip (not labeled). Furthermore, Figure 8 shows the body portion of the stent overlies the second end of the body regions of both grips. It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize two grips as taught by Gunderson in the stent delivery system of Ravenscroft in order to provide a stent delivery system that may reduce or eliminate occurrences of stent jumping, in turn improving the accuracy of stent placement within a vessel or other body space (paragraph 10).

14. Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ravenscroft. Ravenscroft discloses the device as described above, however fails

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to disclose the specific hardness of the grip. It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the grip with a hardness of about 60 to about 90, or of 70 to about 90, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

Response to Arguments

15. Applicant's arguments filed 23 January 2007 have been fully considered but they are not persuasive (see rejection above). With respect to claims 1-10 and 25, applicant argues primarily that the hub region of the grip disclosed by Cox is not disclosed as being abutted by a stent during use. However, this newly added functional limitation has been given limited weight, wherein the hub of Cox is capable of abutting a stent if one desires to place the stent in this configuration.

With respect to claims 16-18, applicant argues primarily that the rejection should be withdrawn since the instant application and the applied reference (Gunderson) have the same assignee. However, the invention disclosed in the applied reference was not derived from the inventor of this application and is thus "by another", which constitutes prior art under 35 U.S.C. 102(e).

16. Applicant's arguments with respect to claims 11-14, 16-24, 26, and 27 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571) 272-9062. The examiner can normally be reached on Monday through Thursday 9-5:30, Fridays 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson
May 16, 2007

MT

Tan-uyen/10

(JACKIE) TAN-UYEN HO
PRIMARY EXAMINER

5/24/07